

Food and Drug Administration, HHS

§ 522.56

522.2640 Tylosin injectable dosage forms.
522.2640a Tylosin injection.
522.2640b Tylosin tartrate for injection.
522.2662 Xylazine hydrochloride injection.
522.2670 Yohimbine injectable.
522.2680 Zeranol.

AUTHORITY: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

SOURCE: 40 FR 13858, Mar. 27, 1975, unless otherwise noted.

§ 522.23 Acepromazine maleate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of acepromazine maleate.

(b) *Conditions of use.* See No. 000856 in § 510.600(c) of this chapter for use in dogs, cats, and horses as follows:

(1) *Indications for use.* It is used in dogs, cats, and horses as a tranquilizer.

(2) *Amount.* Dogs: 0.25 to 0.5 milligram per pound of body weight; Cats: 0.5 to 1.0 milligram per pound of body weight; Horses: 2.0 to 4.0 milligrams per 100 pounds of body weight.

(c) *Conditions of use.* See No. 054273 in § 510.600(c) of this chapter for use in dogs as follows:

(1) *Indications for use.* It is used in dogs as an aid in tranquilization and as a preanesthetic agent.

(2) *Amount.* Dogs: 0.25 to 0.5 milligram per pound of body weight.

(3) *Limitations.* The drug is administered intravenously, intramuscularly or subcutaneously with the dosage individualized depending upon the degree of tranquilization required. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 43831, Sept. 1, 1981, as amended at 53 FR 40727, Oct. 18, 1988]

§ 522.44 Sterile sodium acetazolamide.

(a) *Specifications.* Sterile sodium acetazolamide contains acetazolamide sodium complying with United States Pharmacopeia as a sterile powder with directions for reconstituting the product with sterile distilled water to furnish a product having a concentration of 100 milligrams acetazolamide activity per milliliter.

(b) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an aid in the treatment of dogs with mild congestive heart failure and for

rapid reduction of intraocular pressure.¹

(2) It is administered intramuscularly or intraperitoneally to dogs at a level of 5 to 15 milligrams per pound of body weight daily preferably administered in two or more divided doses.¹

(3) For use only by or on the order of a licensed veterinarian.¹

§ 522.46 Alfaprostol.

(a) *Specifications.* Each milliliter of sterile solution contains 1 milligram of alfaprostol.

(b) *Sponsor.* No. 055882 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used in horses as follows:

(1) *Amount.* For average mature mares, 6.0 micrograms per kilogram of body weight.

(2) *Indications for use.* To cause luteolysis in mares with active corpora lutea.

(3) *Limitations.* For intramuscular or subcutaneous use as a single injection. Not for horses intended for food. Alfaprostol is readily absorbed through the skin and can cause abortion and/or bronchial spasms. Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 43300, Sept. 23, 1983, as amended at 53 FR 40057, Oct. 13, 1988]

§ 522.56 Amikacin sulfate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 50 milligrams of amikacin (as the sulfate).

(b) *Sponsor.* See 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use—*(1) *Amount.* 5 milligrams per pound of body weight twice daily.

(2) *Indications for use.* The drug is used in dogs for treatment of

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.